

## **REMARKS**

This Amendment responds to the Office Action mailed November 8, 2007. Claims 1-34, 36-134 and 136-232 are pending. Of these, claims 40-121 and 171-232 stand withdrawn from further consideration pursuant to a restriction requirement. Claims 35 and 135 have been canceled.

### **Interview**

Applicants would like to thank Examiner Stoklosa for the telephonic interview conducted with the undersigned attorney on January 3, 2008. While no agreement was reached, the Examiner's remarks were helpful in the formulation of this response.

### **Rejection Under § 112**

The Examiner rejected claim 154 under 35 U.S.C. § 112, second paragraph, as being indefinite. Claim 154 has been amended to address the Examiner's concerns. Applicants respectfully suggest that claim 154 now meets the definiteness requirements of § 112.

### **Rejections Under §§ 102(b) and 103 Over Easterbrook**

The Examiner rejected claims 1-3, 9, 12, 14-17, 19, 20, 26-27, 31, 36-39, 122, 136-139 and 143 under 35 U.S.C. § 102(b) as being anticipated by Easterbrook et al. US 6,238,334 ("Easterbrook"). The Examiner rejected claims 4, 7, 8, 10, 11, 13, 18, 159, 160, 169 and 170 under 35 U.S.C. § 103(a) as being unpatentable over Easterbrook. Applicants have amended claims 1 and 122 to recite a compliant first layer fabricated with a material having a minimum of 500% elongation. This subject matter had previously been included in claim 10.

Amended claim 1 recites, among other elements, a device comprising a compliant first layer fabricated from a material having a minimum of 500% elongation adapted to engage internal vasculature, and a second layer coupled to the first layer, the second layer having a stiffness greater than a stiffness of the first layer, wherein the first layer is configured to be deformed in response to a change in the volume of the cavity. Easterbrook, on the other hand, discloses a device in which neither the first and second layer is deformable to the degree now recited by claim 1. For example, Easterbrook's outer shell 12 is "made from a substantially non-

stretchable, yet foldable and bendable material" (col. 5, lines 39-41), and Easterbrook's bladder is "made from a substantially fluid impermeable film (i.e., unyielding and non-stretchable) that is reinforced by a tear-resistant, non-stretchable, preferably woven, material." (col. 6, lines 45-48). Instead of stretching or deforming when inflated, Easterbrook's cuff is inserted in a folded configuration and merely unfolds when inflated. (Easterbrook col. 8, lines 9-12). In addition, Easterbrook does not disclose the use of a material having a minimum of 500% elongation. Since Easterbrook does not disclose every feature of claim 1, Easterbrook cannot anticipate claim 1 or claims 2-34 and 36-39 depending from it. Claims 1-34 and 36-39 are patentable over Easterbrook under § 102(b).

With respect to the rejection under § 103(a), it would not have been obvious to use a material in the Easterbrook device with the elongation properties now recited by claim 1. Because the Easterbrook device is on the heart, Easterbrook specifically requires that the bladder is nonstretchable so that the bladder will not expand to a size that would create a transmural pressure when inflated. (See col. 6, lines 52-54.). To replace the Easterbrook nonstretchable bladder material with a material having a minimum 500% elongation would defeat this design requirement of the Easterbrook device, thereby rendering that substitution nonobvious. Claims 1-34 and 36-39 are therefore patentable over Easterbrook under § 103(a) as well.

Amended claim 122 recites a system including, among other elements, a cuff having a compliant first layer having a minimum of 500% elongation configured to engage internal vasculature and a second layer coupled to the first layer to form a cavity, and a conduit configured to convey fluid to the cuff from the pump to deform the first layer by expanding and contracting the cavity. Easterbrook's device, on the other hand, does not deform either the outer shell or the bladder by expanding and contracting the cavity they form. Instead of deforming as required by claim 122, Easterbrook's bladder folds and unfolds as fluid is conveyed out and in. Easterbrook's cavity always remains the same size; it never expands and contracts as recited by claim 122. In addition, Easterbrook does not disclose the use of a material having a minimum of 500% elongation. Since Easterbrook does not disclose every feature of claim 122, Easterbrook cannot anticipate claim 1 or claims 123-134 and 136-170 depending from it. Claims 123-134 and 136-170 are patentable over Easterbrook under § 102(b).

Finally, as with claim 1, it would not have been obvious to use a material in the Easterbrook device with the elongation properties now recited by claim 122. Because the Easterbrook device is on the heart, Easterbrook specifically requires that the bladder is nonstretchable so that the bladder will not expand to a size that would create a transmural pressure when inflated. (See col. 6, lines 52-54.) To replace the Easterbrook nonstretchable bladder material with a material having a minimum 500% elongation would defeat this design requirement of the Easterbrook device, thereby rendering that substitution nonobvious. Claims 123-134 and 136-170 are therefore patentable over Easterbrook under § 103(a) as well.

#### **Rejection Under § 103 Over Easterbrook and Walsh**

The Examiner rejected claims 5 and 6 under 35 U.S.C. § 103(a) as being unpatentable over Easterbrook in view of Walsh et al. US 6,902,522 ("Walsh"). Claims 5 and 6 depend from claim 1 and are therefore patentable for the reasons stated above with respect to claim 1.

#### **Rejection Under § 103 Over Easterbrook and Franchi**

The Examiner rejected claims 21, 22<sup>1</sup>, 128-129 and 161-164 under 35 U.S.C. § 103(a) as being unpatentable over Easterbrook in view of Franchi US 6,030,335 ("Franchi"). Claims 21 and 22 depend from claim 1 and are therefore patentable for the reasons stated above with respect to claim 1. Claims 128, 129 and 161-164 depend from claim 122 and are therefore patentable for the reasons stated above with respect to claim 122.

#### **Rejection Under § 103 Over Easterbrook and Freed**

The Examiner rejected claims 123-127 and 130-134 under 35 U.S.C. § 103(a) as being unpatentable over Easterbrook in view of Freed US 5,169,379 ("Freed"). Claims 123-127 and 130-134 depend from claim 122 and are therefore patentable for the reasons stated above with respect to claim 122.

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<sup>1</sup> The Examiner did not explicitly reject claim 22 on this basis, but it appears based on the Examiner's remarks that the Examiner intended to do so. Applicants will treat claim 22 as having been rejected over Easterbrook and Franchi.

**Rejection Under § 103 Over Easterbrook and Okuzumi**

The Examiner rejected claims 165-168 under 35 U.S.C. § 103(a) as being unpatentable over Easterbrook in view of Okuzumi US 6,587,734 ("Okuzumi"). Claims 165-168 depend from claim 122 and are therefore patentable for the reasons stated above with respect to claim 122.

**Allowable Subject Matter**

The Examiner indicated that claims 28-30, 32-34, 140-142 and 144-146 would be allowable if rewritten in independent form including all limitations of their base claims and any intervening claims.

**Claims Not Addressed By The Office Action**

The Examiner's Office Action did not address the status of claims 23-25, 37, 38, 147-153 and 156-158. These claims are allowable over the prior art of record for the reasons stated above.

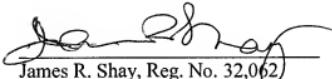
**CONCLUSION**

Applicants request reconsideration and allowance of all claims pending in this application. If a telephone conference would expedite prosecution of this application, the Examiner is invited to contact the undersigned.

Respectfully submitted,

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By:



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